REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 10, 33 and 36-39 have been deemed allowed. Claims 34, 35 and 40 are under current examination.

Claims 10 and 33-40 are currently pending in this application.

Rejection under 35 U.S.C. § 112, First Paragraph

The rejection of claims 34 and 40 under 35 U.S.C. § 112, First Paragraph as allegedly failing to comply with the written description requirement is respectfully traversed.

The proper standard for determining compliance with the written description requirement of 35 U.S.C. § 112, first paragraph, is whether the specification reasonably conveys to the skilled artisan that the inventor was in possession of the claimed invention as of the filing date. *See* MPEP § 2163.02 (*citing Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 USPQ 177, 179 (Fed. Cir. 1985)). The subject matter of the claimed invention need not be described literally in the specification in order to satisfy the requirements of 35 U.S.C. § 112, first paragraph. *Id.* In a careful analysis of the written description requirement provided by the Patent and Trademark Office in its *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1, "Written Description" Requirement*, it is stated that an adequate written description "may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." 66 Fed. Reg. 1099, 1105 (2001) (emphasis added).

Instant claim 34 is directed to a purified, enriched, or isolated nucleic acid sequence, wherein the nucleic acid sequence is at least 90% identical to a portion at least 200 nucleotides in length of the *N. gruberi* thiaminase sequence as set forth in SEQ ID NO:3. Each and every nucleotide of SEQ ID NO:3 is unambiguously described in the application. Selecting a portion of SEQ ID NO:3 that is 200 nucleotides in length is a trivial task to one of ordinary skill in the art as is determining the number of nucleotide bases that would constitute 90% of the selected portion of SEQ ID NO:3. Accordingly, Applicant respectfully submits that the specification provides ample written description to demonstrate that the inventor was in possession of the entire genus of nucleotide sequences encompassed by the instant claims.

The Examiner further alleges lack of written description because "[t]here are no drawings or structural formulas disclosed of any other protein fragment, encompassed by the claims, that would encode a protein with a thiaminase activity, other than the full length SEQ ID NO:3." Office Action, p. 3, lines 20-23. As described above, one of ordinary skill in the art could readily make a protein at least 200 nucleotides in length having 90% or 95% sequence identity to SEQ ID NO:3. With respect to requirements for thiaminase activity, Examples 1-3 of the specification provide experiments of how to test for such activity. As such, one of ordinary skill in the art, using the specification as a guide, could readily determine whether a particular protein encoded by a nucleic acid sequence does or does not have the requisite thiaminase activity without undue experimentation. Thus, one of ordinary skill in the art would understand that the inventors had possession of the full scope of the claims. As such, additional drawings or structural formulas are not required to satisfy the 35 U.S.C. § 112, first paragraph written description requirement.

Applicant respectfully submits that the Examiner's assertion at pages 4-5 of the office action suggesting that the fact that a 200 nucleotide segment is 18.7% percent of the total length of SEQ ID NO:3 is irrelevant to a determination as to whether there is adequate written description for the instant claims. In this regard, each and every nucleotide of SEQ ID NO:3 is provided in the application, therefore each nucleotide of every possible 200 nucleotide segment of SEQ ID NO:3 is also inherently described in the application. As described above the

determination of sequences that are 90% identical to such segments is trivial to one of ordinary skill. Thus, because each amino acid of SEQ ID NO:3 is explicitly described in the application, the fact that the instant claims need only encompass a portion (e.g., 18.7%) of the fully described sequence bears no relevance as to whether the sequence, or segments thereof, are described.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the written description rejection.

Rejection under 35 U.S.C. § 112, First Paragraph

The rejection of claims 34, 35 and 40 under 35 U.S.C. § 112, First Paragraph, for alleged lack of enablement is respectfully traversed.

In this rejection, the Examiner acknowledges that the specification is enabling for a purified, enriched or isolated nucleic acid sequencing consisting of SEQ ID NO:3, however, alleges that the specification does not reasonably provide enablement for fragments of SEQ ID NO:3 with 90% or 95% homology or with thiaminase activity. Contrary to the Examiner's assertion, one of ordinary skill could make and use nucleic acid sequences as claimed without undue experimentation.

(1) The Nature of the Invention and (2) The Breadth of the Claims

The instant claims are directed to eukaryotic expression vectors comprising recombinant nucleic acid sequences encoding thiaminase I from *N. gruberi* as set forth by a specified nucleic acid sequence (SEQ ID NO:3) and fragments thereof. The claims are limited to very specific nucleic acid sequences that have a high level of homology (i.e., 90%) to a single specific nucleic acid sequence. The scope of the claims is clear and finite. The specific focus of the claims weighs the Wands factors relating to the nature of the invention and the breadth of the claims heavily in favor of enablement of the instant claims.

(3) Relative Skill of Those in the Art

Those of ordinary skill in the art related to the instant claims, i.e., enzyme molecular biology, have a relatively high level of skill, i.e., they would generally have an advanced degree such as a masters or Ph.D. and would be able to identify and make variations of a given nucleic acid sequence and test such variants for a particular enzymatic activity according to a given protocol. This relatively high skill in view of the claims further weighs in favor of enablement of the claims.

(4) The Amount of Direction or Guidance Presented, and (5) The Presence or Absence of Working Examples

The Examiner acknowledges that "the specification provides guidance for utilizing nucleic acid sequences that encode polypeptides that have thiamin-binding activity for various *in vitro* and *in vivo* uses." Office Action, p. 7, lines 6-8. The specification also provides working examples of assays for detecting and measuring thiaminase activity and cites to several other methods available for assaying thiaminase activity. *See* Example 1. The specification also provides a working example for making and expressing recombinant nucleic acid sequences encompassed by the claims. *See* Examples 3 and 4; and Table 2. The specification further provides an example of a Cys to Ser mutation that inactivates enzymatic activity, thus providing a site possibly responsible for enzymatic activity. *See e.g.*, p. 18, lines 24-27; and Example 3. Accordingly, in addition to specific examples provided in the specification, the specification provides ample guidance and direction to detect and measure enzymatic activity using only routine experimentation.

As such, when all of the teachings, examples and experimental data provided in the application are considered, the Wands factors relating to the amount of direction or guidance presented and the presence or absence of working examples weigh heavily in favor of enablement of the instant claims.

(6) The Quantity of Experimentation Necessary, (7) The State of The Prior Art, and (8) The Predictability of the Art

The Examiner alleges that fragments and variants encompassed by the claims are not enabled. Contrary to the Examiner's assertion, one of ordinary skill in the art could readily identify, make and use fragments and variants encompassed by the claims. The claims are based upon one specific nucleic acid sequence, SEQ ID NO:3. One of ordinary skill in the art could systematically identify each and every possible fragment and variant of SEQ ID NO:3 encompassed by the claims. Moreover, each fragment and variant could be tested by routine experimentation. While there may be numerous possibilities, a considerable amount of experimentation is permitted, provided that it is merely routine, or provided that the specification provides a reasonable amount of guidance for the experimentation needed. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). As described above, one of ordinary skill in the art, relying only on the description clearly provided in the specification together with trivial procedures well known in the art, could readily practice the entire scope of the claims. As such, no level of experimentation that is undue would be required to practice the scope of the claims.

Accordingly, when all of the teachings, examples and experimental data provided in the application are considered, the Wands factors relating to the quantity of experimentation necessary; the state of the prior art, and the predictability of the art also weigh in favor of enablement of the claims.

Summary

The standard for determining enablement is whether the specification as filed provides sufficient information as to permit one skilled in the art to make and use the claimed invention. *United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The test of enablement is not whether experimentation is necessary, but rather whether any experimentation that is necessary is undue. *Id.* As described above a balance of the Wands factors falls in favor of enablement of the instant claims because given Applicant's disclosure, one of ordinary skill in the art could readily and routinely identify, make and test nucleic acid sequences to determine

what would and would not fall within the scope of the claims. Thus, no *prima facie* enablement rejection exists. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 05/21/2009

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